

REMARKS

Claim 23 is pending in this application. Claim 23 was rejected under 35 U.S.C. §101 and under 35 U.S.C. §102(b).

By this amendment, claim 23 has been amended and new claims 29-39 have been added without prejudice or disclaimer of any previously claimed subject matter. Support for the amendment to claim 23 can be found, *inter alia*, throughout the specification, for example, at page 17, lines 23-28, and page 21, lines 16-20. Support for new claims 29 and 38 can be found, *inter alia*, at page 17, line 23, to page 18, line 10. Support for new claims 30 and 31 can be found, *inter alia*, at page 17, lines 3-9. Support for new claims 32, 33, 37, and 39 can be found, *inter alia*, at page 19, lines 1-22. Support for new claims 34-36 can be found, *inter alia*, at page 18, lines 11-23.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants believe that the Examiner's concerns have been addressed as described herein.

Rejection under 35 U.S.C. §101

Claim 23 was rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. Applicants respectfully traverse this rejection.

Although Applicants believe that the previous claim was directed to statutory subject matter, i.e., a polynucleotide encoding an apo-B100 protein comprising a mutation in Site B which

results in a proteoglycan– receptor+ phenotype, Applicants have taken the Examiner’s suggestion and amended the claims to be directed to an isolated and purified polynucleotide encoding an apo-B100 protein comprising a proteoglycan– receptor+ phenotype.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §101.

Rejections under 35 U.S.C. §102(b)

Claim 23 was rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Law *et al.* (1990, *J. Lipid Research* 31:1109-1120, “Law”). Applicants respectfully traverse this rejection.

For a claim to be anticipated by a reference, the reference must teach each and every element of the claim.

As discussed in the specification, the invention is directed to a polynucleotide encoding an apo-B100 protein that comprises a mutation in Site B which results in a proteoglycan– receptor+ phenotype, i.e., an apo-B100 protein with reduced binding activity to proteoglycan but with normal binding activity to the LDL receptor. Herein, the claims have been amended to specifically point out amino acid alterations in site B of the apo-B100 protein that result in the mutant phenotype.

Thus, the claimed invention is directed to an isolated and purified polynucleotide encoding an apo-B100 protein comprising a mutation in Site B, wherein Site B is equivalent to amino acids from about 3358 to about 3369 of the human apo-B100 protein and wherein the mutation comprises at least one amino acid substitution or deletion of at least one of Lys₃₃₆₃, Arg₃₃₆₂, or Arg₃₃₆₄. The claimed invention is also directed to an isolated and purified polynucleotide encoding an apo-B100 protein comprising a mutation in Site B, wherein the mutation comprises at least one amino acid addition to site B. The claimed invention is also directed to an isolated and purified polynucleotide encoding an apo-B100 protein comprising a mutation in Site B, wherein the

mutation comprises a deletion of amino acid Arg₃₃₅₉ or a substitution of amino acid Arg₃₃₅₉ by an amino acid as specifically claimed.

Law describes polynucleotide sequences that encode the amino acid sequence of a number of apo-B100 proteins from a variety of animal species. The Examiner points to the teaching in Law that the rabbit apo-B protein contains two different amino acids in the human equivalent positions 3358 and 3359 and that the pig apo-B protein contains amino acid differences from human at positions 3358, 3359, and 3361. Office Action, page 4. Applicants respectfully submit, however, that Law is silent with regard to a polynucleotide encoding an apo-B100 mutant protein as claimed and with regard to an apo-B100 mutation in Site B which results in a proteoglycan– receptor+ phenotype. Thus, Law does not teach the claimed invention.

Accordingly, Applicants respectfully submit that Law does not anticipate the claimed invention.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 220002059711.

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Respectfully submitted,

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